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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,890	01/07/2002	Craig E. Smith	016026-9148	5555

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EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,890	SMITH ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 22-56* is/are pending in the application.

4a) Of the above claim(s) *29-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6, 22-28 and 29-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 22-28, drawn to a method of isolating a biological target material from other material in a medium, classified in class 435, subclass 4.

II. Claims 29-56, drawn to a kit for isolating nucleic acids, classified in class 435, subclass 4.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of isolating nucleic acids can be practiced with other kits and reagents available for nucleic acid isolation.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jill Fahrlander on May 26, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6 and 22-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Josephson (USPN 4,672,040 06/09/1987).

Josephson teaches a method for isolating biological target material from other material in a medium by contacting the medium with the biological target with silica magnetic particles that reversibly bind the target to create a complex of the magnetic particle and the target material (see whole document, especially col. 18 lines 44-68, col. 7 lines 66-67, col. 8 lines 1-9). He teaches removing the complex from the medium with a magnet, and separating the target material from the complex by eluting and obtaining the target material (see col. 30 lines 55-60). Additionally, he teaches nucleic acids as isolated materials (see col. 16 lines 18). He also teaches using siliceous oxide coated magnetic particles (see col. 7 lines 66-67, col. 8 lines 1-5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 5, 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson (USPN 4,672,040 06/09/1987) in view of Gautsch et al. (USPN 6,613,895 B1 09/02/2003).

Josephson teaches a method for isolating biological target material from other material in a medium by contacting the medium with the biological target with silica magnetic particles that reversibly bind the target to create a complex of the magnetic particle and the target material (see whole document, especially col. 18 lines 44-68, col. 7 lines 66-67, col. 8 lines 1-9). He teaches removing the complex from the medium with a magnet, and separating the target material from the complex by eluting and obtaining the target material (see col. 30 lines 55-60). Additionally, he teaches nucleic acids as isolated materials (see col. 16 line 18). He also teaches using siliceous oxide coated magnetic particles (see col. 7 lines 66-67, col. 8 lines 1-5).

Josephson does not teach magnetic silica particles capable of binding at least 2 micrograms of the biological target. He does not teach 60% of the biological target eluted from the particles. He also does not teach using a chaotropic salt, incubating the mixture of magnetic particles with the target at room temperature or a washing step with a wash buffer.

Gautsch et al. teach silica particles capable of binding at least 2 micrograms of a biological target, specifically nucleic acids (see whole document, especially col. 4 lines 49-51). They also teach at least 60% of target material, specifically nucleic acids, eluted from the complex of silica particles and target material (see col. 14 lines 30-40). Furthermore they teach a method of isolating plasmid DNA from other materials in a medium using silica particles and a chaotropic salt to help the DNA adhere to the silica particles (see col. 13 line 24, col. 8 lines 48-54). They also teach the chaotorpic salt as guanidine thiocyanate (see col. 5 lines 6-12). They

teach a salt concentration of between 0.1 M and 7 M (see col. 5 lines 62-63). Additionally they teach washing the silica particles after removing them from the medium before eluting the bound DNA (see col. 8 lines 61-66). They teach the wash buffer as a mixture of alcohol and salt, at least 30% by volume (see col. 11 lines 28-30).

One of ordinary skill in the art at the time the invention was made one would have been motivated to apply Josephson's silica coated magnetic particles to Gautsch's method of isolating nucleic acid with silica particles to achieve more rapid and simplified separations of target analytes. Josephson states magnetic particles are selectively recovered, promote homogenous reaction conditions and facilitate separation of bound from unbound analytes (see col. 2 lines 66-67 and col. 3 lines 1-2). It would have been prima facie obvious to apply Josephson's magnetic silica particles to Gautsch's method of isolating nucleic acids in order to achieve the expected advantage of a cleaner method isolating nucleic acids that is less time consuming and yields a cleaner product.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,027,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because

claims 1-6 of the instant application are drawn to a method of isolating a biological target material, more specifically a nucleic acid, comprising contacting the medium containing the target with silica magnetic particles that reversibly bind at least 2 micrograms of the target, forming a complex between the target and the magnetic particles, removing the complex with an external magnetic field and eluting at least 60% of the target from the particles. Claims 1-6 of USPN 6,027,945 are drawn to first providing the medium containing the biological target material, more specifically a nucleic acid, providing the silica magnetic particles that reversibly bind the target and then forming a complex between the magnetic particles by combining the particles and the medium, then removing the complex with an external magnetic field and eluting at least 60% of the target from the particles. In the instant application the small variation in the method steps does not render the invention unobvious in the overall design when compared to USPN 6,027,945.

5. Claims 22-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-28 of U.S. Patent No. 6,027,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-28 of the instant application are drawn to a method of isolating a biological target material, more specifically a plasmid DNA, comprising forming a mixture comprising a medium with the plasmid DNA, siliceous oxide coated magnetic particles that reversibly bind at least 2 micrograms of the plasmid DNA, a guanidinium chaotropic salt wherein the concentration of the salt is sufficient to cause the DNA to adhere to the particles when incubated at room temperature, removing the complex with an external magnetic field, washing with a solution that is at least 30% alcohol by volume and buffer and then eluting at least 60% of the target from the particles. Claims 22-28 of USPN 6,027,945 are drawn to first providing the medium containing the plasmid DNA, providing the silica magnetic particles that reversibly bind at least 2

micrograms of the DNA and then forming a mixture comprising a medium with the plasmid DNA, siliceous oxide coated magnetic particles that reversibly bind at least 2 micrograms of the plasmid DNA, a guanidinium chaotropic salt wherein the concentration of the salt is sufficient to cause the DNA to adhere to the particles when incubated at room temperature, removing the complex with an external magnetic field, washing with a solution that is at least 30% alcohol by volume and buffer and then eluting at least 60% of the target from the particles. In the instant application the small variation in the method steps does not render the invention unobvious in the overall design when compared to USPN 6,027,945.

Summary

6. No claims were allowed.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on weekdays 7:30 A.M. - 4:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
6/2/04